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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/669,656	06/24/1996	JOHN N WOOD	70086	2420

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EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1631

26

DATE MAILED: 02/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/669,656

Applicant(s)

WOOD ET AL.

Examiner

Marianne Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-10, 13, 14, 17-33 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9, 10, 13, 14 and 18-29 is/are allowed.
- 6) ☒ Claim(s) 8, 17, 30-33, 38-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/19/01 has been entered.

Claim 40 has been newly introduced. Claims 8-10, 13-14, 17-33, and 38-40 are under consideration by the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed 11/19/01 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant points to basis in original claim 1, Example 2.5, and Example 12. Claim 11 specifies no hybridization conditions. Example 2.6 disclosed the recited hybridization conditions but with respect to probes derived from the 3' untranslated region coupled to additional hybridization screening. No particular required functional activities are disclosed in

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this example. Example 12 discusses hybridization but not in the context presently claimed. It is directed to *in situ* hybridization and not cloning and recovery of sequences. New claim 40 recites "specifically hybridizes." The metes and bounds of what this is intended to mean are not disclosed in the named portions of the specification. This concept does not appear to have been contemplated. As such, the newly claimed subject matter of claim 40 does not appear to be described nor contemplated by the specification as originally filed.

Claims 8, 17, 30-33, and 38-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

This rejection is maintained for reasons of record and as reiterated below.

Claim 8 is directed to a nucleic acid sequence encoding the sodium channel protein of SEQ ID NO: 2, 4, 6, or 8 or the complement of the nucleic acid sequence. Claims 30-33 are directed to nucleic acid sequences encoding each of SEQ ID NOS: 2, 4, 6, 8, and 2, individually. Claim 17 is directed to a method of producing the protein using the sequence of claim 8. Claim 38 is directed to a vector containing the sequence of claim 38 and claim 39 is directed to a host cell containing the sequence of claim 8.

The claims language of claims 8 and 30-33 are being interpreted as being open (i.e. comprising) and not limited to just the coding portions. As such, the claims encompass the genomic sequences which are in fact contemplated by the disclosure. (See page 5, last line.)

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Applicant's response concedes that the claims encompass genomic sequences even though they state that the claims are "claimed in a manner which does not specifically recite a gene." (See response at page 3, lines 9-11, and page 4, lines 4-7.) While the specification discloses various cDNAs, the specification fails to provide a written description of the structure of the genomic DNA (i.e. introns, exons, non-coding) sequences, including any splice variants of the gene.

The pertinent case law has been discussed in prior Office actions and is briefly summarized here.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed gene or genomic polynucleotides regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

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...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

The specification provides no description by words, structures, figures, diagrams, or sequence for any genomic sequence corresponding to any nucleic acid encoding SEQ ID NOS: 2, 4, 6, or 8, or a complement thereof. No member of the genomic sequence subgenus is disclosed.

Applicant's arguments with respect to the Written Description Guidelines (published in either 1999 or 2001) and the training materials available on the PTO website are not persuasive. First of all, the examiner did not provide the applicant with the training materials attached to the response. The examiner pointed applicant to the PTO website. The availability date of the training materials or publication date of these training materials is not known by the examiner. The examiner does not concede or agree that the 2001 Guidelines supersede the training materials. The examiner is not aware of any new training materials that have been published or disseminated to patent examiners. The examiner reminds applicant that guidelines and training

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materials are just that. They do not have the force of law (35 U.S.C.) or a rule (37 C.F.R.).

Absence of an example, comment, or discussion with respect to applicant's particular fact pattern does not obviate or mandate a rejection. Thus, arguing about conclusions with respect to other fact patterns or examples or comments in these materials is not germane to the rejection in this application. The rejection in this application is and has always been based upon the particular fact pattern present in the specification and set forth on the record and in view of the pertinent case law which has also been set forth on the record. The determination of whether a rejection is appropriate is made based upon the facts and the law.

Applicant has failed to provide a persuasive argument as to why the information in their specification describes any or all genomic sequences embraced by the claims. The subgenus of cDNA sequences and degenerate versions of the coding regions does not describe the subgenus of genomic sequences encompassed by the claims. The claims embrace both subgenres. The description provided in the specification is insufficient to support the breadth of the claims.

Claim Rejections - 35 USC § 102

Claim 40 is rejected under 35 U.S.C. 102(e) as being anticipated by Herman et al. (U.S. Patent No. 6,184,349).

SEQ ID NO: 1 of Herman et al. has high but not identical identity to SEQ ID NO: 1 of the instant application. This sequence encodes a tetrodotoxin-resistant sodium channel protein. The sequence of Herman et al. would be expected to specifically hybridize to SEQ ID NO: 1 of the instant application under the recited conditions. SEQ ID NO: 1 of Herman et al. is disclosed in parent application 08/511,828 filed 10/11/95. Thus, the '349 patent is valid prior art against the instant application.

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Conclusion

Claims 8, 17, 30-33, and 38-40 are rejected. Claims 9-10, 13-14, and 18-29 remain allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Friday from 7:00 am to 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028. Official FAX communications may be directed to either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning the formalities of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 308-0009.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
~~GROUP 1500~~
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